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Patent Docket P1085R3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Vanessa Hsei et al. Serial No.: 09/355,014 Filed: July 21, 1999 For: ANTIBODY FRAGMENT- POLYMER CONJUGATES AND HUMANIZED ANTI-IL-8 MONOCLONAL ANTIBODIES	Group Art Unit: 1642 Examiner: L. Helms <div><p>CERTIFICATE OF MAILING</p><p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on</p><p><i>[Signature]</i>, 2001</p><p><i>[Signature]</i> Yvonne Carter</p></div>
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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This application is related to co-pending application U.S. Serial No. 08/804,444 filed February 21, 1997, now granted as U.S. Pat. No. 6,117,980, co-pending application U.S. Serial No. 09/012,116 filed January 22, 1998, now abandoned, co-pending application U.S. Serial No. 09/026,985 filed February 20, 1998, now granted as U.S. Pat. No. 6,133,426, co-pending application U.S. Serial No. 09/027,449 filed February 20, 1998, now granted as U.S. Pat. No. 6,025,158, co-pending application U.S. Serial No. 09/121,952 filed July 24, 1998, co-pending application U.S. Serial No. 09/122,513 filed July 24, 1998, now abandoned, co-pending application U.S. Serial No. 09/234,340 filed January 20, 1999, co-pending application U.S. Serial No. 09/234,182 filed January 20, 1999, co-pending application U.S. Serial No. 09/726,258 filed November 29, 2000, co-pending application U.S. Serial No. 09/254,909 filed March 16, 1999, and co-pending application U.S. Ser. No. 09/489,394 filed January 21, 2000.

On or about May 21-25, 1995, a poster entitled "Site-Specific Coupling of

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Monomethoxypoly(ethylene glycol) to a Single-Sulfhydryl Humanized Fab" naming as authors Gerardo Zapata, Dorothy Bates, Monika Schoenhoff, Jim Deveney, Steve Frie, Brad Snedecor, Paul Carter and Steven M. Chamow was presented at a poster session of the American Society for Biochemistry and Molecular Biology FASEB Meeting held on May 21-25, 1995. All of the information that was disclosed in the aforementioned poster is contained in a 27 page reproduction of the poster enclosed with the present Information Disclosure Statement.

On February 23, 1997, a poster entitled "Humanization of Murine 6G425: An Anti-IL-8 Monoclonal Antibody which Blocks Binding of IL-8 to Human Neutrophils" naming as authors Tania N. Gonzalez, Steven R. Leong, Rhona Kabakoff, Caroline Hebert and Leonard G. Presta was presented at a poster session of the 1996 Keystone Symposia on Exploring and Exploiting Antibody and Ig Superfamily Combining Sites held on February 23-24, 1996. All of the information that was disclosed in the aforementioned poster is contained in a 21 page reproduction of the poster enclosed with the present Information Disclosure Statement.

On or about July 25-29, 1998, an abstract entitled "Tailoring Antibody Fragments with PEGylation without Loss in Biological Activity" naming as authors Iphigenia L. Koumenis, Gerardo Zapata, Steve Leong, Vanessa Hsei and Zahra Shahrokh was presented at The Protein Society 12th Symposium held on July 25-29, 1998. The abstract was published in Protein Science, 7(Suppl. 1):73 (July, 1998), Abstract #109-M, a copy of which is enclosed with the present Information Disclosure Statement.

This Information Disclosure Statement is filed in accordance with the provisions of:

[x] **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

[] **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

[] **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) and a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. , filed and relied upon in this application for an earlier filing date under 35 USC §120.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-0" (nucleotide) and "BLAST Results B-1 - B-0" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

☐ not given

☐ given for each listed item

☒ given for only non-English language listed item(s) [Required]

For item number 32 (WO 96/02576), an English abstract is attached.

For item number 39 (WO 97/40215), an English abstract is attached.

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

In the event that the Office determines a fee to be due where none is specifically authorized in this paper, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p).

Respectfully submitted,

GENENTECH, INC.

Date: March 8, 2001

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FORM PTO-1449

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LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Hsei et al.

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Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	1	4,002,531	11.01.77	Royer			
	2	4,179,337	18.12.79	Davis et al.			
	3	4,732,863	22.03.88	Tomasi et al.			
	4	5,147,537	15.09.92	Sada et al.			
	5	5,166,322	24.11.92	Shaw et al.			
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	7	5,527,528	18.06.96	Allen et al.			
	8	5,532,150	02.07.96	Snow et al.			
	9	5,595,732	21.01.97	Hakini et al.			
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	18	5,698,196	16.12.97	Matsushima et al.			
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	23	770,628	02.05.97	EPO				
	24	WO 92/04372	19.03.92	PCT				
	25	WO 94/12219	09.06.94	PCT				
	26	WO 94/21235	29.09.94	PCT				
	27	WO 95/11987	04.05.95	PCT				
	28	WO 95/15769	15.06.95	PCT				
	29	WO 95/23813	08.09.95	PCT				
	30	WO 95/23865	08.09.95	PCT				
	31	WO 95/32003	30.11.95	PCT				
	32	WO 96/02576	01.02.96	PCT (ENGLISH ABSTRACT ATTACHED)				
	33	WO 96/09325	28.03.96	PCT				

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Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes	No
	34	WO 96/22785	01.08.96	PCT				
	35	WO 96/34015	31.10.96	PCT				
	36	WO 96/40731	19.12.96	PCT				
	37	WO 97/01354	16.01.97	PCT				
	38	WO 97/10847	27.03.97	PCT				
	39	WO 97/40215	30.10.97	PCT (ENGLISH ABSTRACT ATTACHED)				
	40	WO 98/25971	18.06.98	PCT				
	41	WO 98/37200	27.08.98	PCT				
	42	WO 99/37779	29.07.99	PCT				

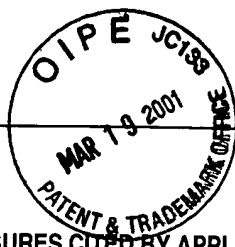
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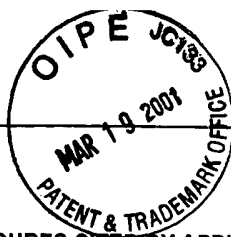
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Examiner

Date Considered

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